IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant:	Palmaz, et al.	Attorney Docket No.:	6006-015
Serial No.:	09/707,685	Examiner:	Cheryl L. Miller
Filed:	November 7, 2000	Art Unit:	3738
		Confirmation No.:	9696

Title: ENDOLUMINAL STENT, SELF-SUPPORTING ENDOLUMINAL GRAFT AND METHODS OF MAKING SAME

CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this document (along with any being referred to as enclosed and/or attached) are being filed electronically on this the 30th day of April, 2007, addressed to: Mail Stop Appeal Brief – Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lori Dunham

Lori Dunham

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1440

APPELLANT'S BRIEF ON APPEAL

1. Real Party in Interest

The real party in interest for this patent application is Advanced Bio Prosthetic Surfaces, L.L.C., the assignee of the application.

2. Related Appeals and Interferences

The following appeals are pending in patent applications that are commonly owned with the present application. While Applicants do not believe that these pending appeals will directly affect or be directly affected by the Board's decision in the present appeal, Applicants disclose these pending appeals due to the common ownership of the patent applications in question.

1. U.S. Patent Application Serial No. 09/716,146 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and Method of Manufacture Thereof, filed on November 17, 2000. (Attorney Docket No. 6006-018)

2. U.S. Patent Application Serial No. 09/783,633 to Bailey et al., for In Vivo Sensor and Method of Making Same, filed on February 14, 2001. (Attorney Docket No. 6006-009)

3. U.S. Patent Application Serial No. 10/258,087 to Boyle et al., for Device for In Vivo Delivery of Bioactive Agents and Method of Manufacture Thereof, filed on August 19, 2003. (Attorney Docket No. 6006-070)

4. U.S. Patent Application Serial No. 10/672,695 to Boyle et al., for Implantable Graft and Methods of Making Same, filed on September 26, 2003. (Attorney Docket No. 6006-107)

No decisions have been rendered by a court or by the Board in any of the aforementioned pending appeals identified pursuant to 37 C.F.R. § 41.37(c)(ii).

3. Status of Claims

Claims 1-38 and 54-66 have been cancelled. Claims 39-53 and 67-74 are pending and stand rejected under 35 U.S.C. § 112, first paragraph and under 35 U.S.C. § 102(e). The rejection of claims 39-53 and 67-74 is under appeal.

4. Status of Amendments

No amendments to the claims were filed after final rejection.

5. Summary of Claimed Subject Matter

Claims 39, 47, and 67 are independent claims in the pending application. Antecedent support for each element in claims 39, 47, and 67 is noted in the parentheses following each claim element:

Claim 39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter (page 16, lines 6-11; page 32, lines 1-2), and having a plurality of first structural elements defining a longitudinal axis of the stent (page 4, lines 7-10; page 5, lines 3-10; page 20, lines 22-24) and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent (page 4, lines 10-16; page 5, lines 10-15; page 20, lines 24-30), comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (page 13, lines 18-29) to form a generally tubular, unpatterned crystalline metal film (page 11, line 30 – page 12, line 4; page 13, lines 6-7) under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material (page 14, lines 19-29);

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film (page 4, lines 5-12; page 13, lines 23-29); and

c. removing the endoluminal stent from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

Claim 47. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter (page 16, lines 6-11; page 32, lines 1-2), and having a plurality of first structural elements defining a longitudinal axis of the stent (page 4, lines 7-10; page 5, lines 3-10; page 20, lines 22-24) and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent (page 4, lines 10-16; page 5, lines 10-15; page 20, lines 24-30), comprising the steps of:

a. vacuum depositing nickel and titanium onto an exterior surface of a generally cylindrical substrate to form an as-deposited generally tubular, crystalline nickel-titanium shape memory film (page 11, line 30 – page 12, line 2; page 14, lines 12-18) having no less than about 51.5 atomic percent nickel (page 11, line 30 – page 12, line 2; page 14, lines 12-18), the vacuum deposition occurring under vacuum deposition process conditions selected to minimize formation of inter- and intra-granular precipitates in the bulk material of the nickel-titanium crystalline film (page 11, line 30 – page 12, line 2; page 14, lines 19-29); and

b. removing the endoluminal stent from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

Claim 67. A method of manufacturing a medical device (page 16, lines 6-11; page 32, lines 1-2), comprising the steps of:

a. vacuum depositing a device-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate (page 13, lines 18-29) to form a generally tubular, unpatterned crystalline metal film (page 11, line 30 – page 12, line 2; page 14, lines 12-18) under vacuum deposition process conditions selected to substantially eliminate formation of chemical and intra- and intergranular precipitates in the bulk material (page 14, lines 19-29); and

b. removing the deposited generally tubular metal film from the generally cylindrical substrate (page 12, line 29 – page 13, line 5; page 32, line 10).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-53 and 67-74 are unpatentable under 35 U.S.C. § 112, first paragraph for purportedly failing to comply with the written description requirement. Whether claims 39-53 and 67-74 are unpatentable under 35 U.S.C. § 102(e) over U.S. Patent Application Publication No. 2003/0018381 to Whitcher et al. (hereinafter referred to as "*Whitcher*").

7. Argument

I. The Examiner's rejection of claims 39-53 and 67-74 under 35 U.S.C. § 112, first paragraph for purportedly failing to comply with the written description requirement is improper and should be withdrawn.

Pursuant to MPEP § 2163 II(A):

> The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a **strong presumption** that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96. [Emphasis added].

Likewise, pursuant to MPEP § 2163.04:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a **preponderance** of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Werheim*, 541 F.2d at 263, 191 USPQ at 97. [Emphasis added].

In the Final Office Action mailed on November 2, 2006, page 3, the Examiner alleges that "[n]owhere in the specification did the examiner find support for deposition of a *crystalline* film layer." The Examiner then contradicts herself in the Advisory Action mailed on February 13, 2007, wherein she alleges that the "exact crystal structure of an as deposited film is not supported... There is ONE mention in the specification of the word crystalline..." Applicants

respectfully disagree with the Examiner's finding (or more appropriately, lack thereof). As acknowledged by the Examiner, page 11, line 30 – page 12, line 4 of Applicants' originally filed application describes, "[w]hen employing vacuum deposition methodologies, the **crystalline structure** of the deposited film affects the mechanical properties of the deposited film." [Emphasis added]. In addition, as omitted by the Examiner, page 13, lines 6-9 of Applicants' originally filed application describes, "[t]he resulting stent may then be subjected to post-deposition processing to modify the **crystalline structure**..." [Emphasis added]. Accordingly, the Examiner's assertion that "[t]here is ONE mention in the specification of the word crystalline" is indisputably and factually wrong.

The Examiner further argues that "nowhere does the specification disclose that these forms [amorphous, monocrystalline, nanocrystalline] are present before post treatment and during deposition." *See* Final Office Action mailed on November 2, 2006, page 4. In the Advisory Action mailed on February 13, 2007, the Examiner asserts that "the specification is referring the [*sic*] how crystallinity may be adjusted or controlled, not that a deposited film has been deposited in a specific crystalline state." Applicants are baffled by these particular remarks. While Applicants are claiming that the as-deposited film be crystalline, Applicants are not claiming (and have not claimed) that the crystalline structure be in any particular state, *i.e.*, amorphous (which is non-crystalline), monocrystalline (which is a single crystal, and generally understood not to be applicable to metal film biomaterials, *see, e.g.*, *Whitcher* [0039] and [0040] teaching single crystal filament or wire, not film materials), or nanocrystalline. *Whitcher*, the reference cited by the Examiner to form an anticipation rejection against the pending claims, however, does describe crystalline forms being amorphous, monocrystalline, and nanocrystalline. *See, e.g.*, claim 1 of *Whitcher*. Applicants respectfully suggest that the Examiner may have confused the disclosure of the pending application with that of *Whitcher*. There is no requirement that a pending application must have support in its specification for the claims of a prior art reference. Accordingly, the Examiner's arguments that "nowhere does the specification disclose that these forms [amorphous, monocrystalline, nanocrystalline] are present before post treatment and during deposition" and that "the specification is referring the [*sic*] how

crystallinity may be adjusted or controlled, not that a deposited film has been deposited in a specific crystalline state" are illogical and are not relevant to the present application.

The Examiner also argues that "the specification does not support deposition of an as deposited crystalline film ... no support in the specification was found ..." Again, Applicants kindly reference page 11, line 30 – page 12, line 4 of Applicants' originally filed application, which describes "[w]hen employing vacuum deposition methodologies, the **crystalline structure** of the deposited film affects the mechanical properties of the deposited film." [Emphasis added]. Applicants also reference page 13, lines 6-9 of Applicants' originally filed application, which describes "[t]he resulting stent may then be subjected to post-deposition processing to modify the **crystalline structure**..." [Emphasis added]. As is clear to a reader skilled in the stent arts, Applicants disclose a vacuum deposition methodology that deposits a film in crystalline form. While the stent or resulting film may be subjected to post-deposition processing to modify the already existing crystalline film, the deposited film is nonetheless already in crystalline form. Accordingly, contrary to the Examiner's assertions, there is clear support for an "as-deposited crystalline film."

Lastly, Applicants submit that under the standard set forth by the MPEP (described above) and by the supporting caselaw pertaining to the written description requirement, the description of the pending application clearly establishes that Applicants had possession of the claimed invention, *i.e.*, vacuum deposition of a crystalline film layer, at the time the original application was filed. Thus, the written description requirement has been met. Moreover, as noted above, it is the Examiner who has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicants submit that the Examiner's mere conclusory statements (recited above), alleging that the written description requirement is not met, lack supporting evidence and do not meet the "preponderance of evidence" standard set forth by the courts. Accordingly, the Examiner's 35 U.S.C. § 112, first paragraph rejection, for purportedly failing to comply with the written description requirement, is without merits and improper. Thus, Applicants kindly request that the Board withdraws the 35 U.S.C. § 112, first paragraph rejection of claims 39-53 and 67-74.

II. The Examiner's anticipation rejection of claims 39-53 and 67-74 under 35 U.S.C. § 102(e) over *Whitcher* is improper and should be withdrawn.

For a prior art reference to anticipate a claim, the prior art reference must teach every element of the claim. *See* MPEP § 2131; *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (holding that "[t]he *identical* invention must be shown in as complete detail as is contained in the ... claim." [Emphasis added].); *see also Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987) (stating that anticipation requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"). Additionally, while an identity of terminology is not required, the elements must nonetheless be arranged as required by the claim. *See In re Bond*, 910 F.2d 831, 832-833 (Fed. Cir. 1990) (holding that anticipation can not be established by mere equivalents). The Examiner has failed to establish that *Whitcher* anticipates the claims on appeal because *Whitcher* does not teach, expressly or implicitly, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film. Applicants submit that independent claims 39, 47, and 67, and claims dependent therefrom, specifically dependent claims 40, 41, 42, 43, 44, 45, 46, 48, 49, 50, 51, 52, 53, 68, 69, 70, 71, 72, 73, and 74, are patentable over the prior art cited and of record.

The claimed invention is generally directed toward a method for manufacturing an endoluminal stent comprising, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film.

According to the Examiner in the Final Office Action mailed on November 2, 2006:

> Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure ... What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there

> is little or a lot of precipitates changes depending on the users [*sic*] *selection* of the condition). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeal Federal Circuit. [Emphasis added].

Contrary to the Examiner's assertions in the Final Office Action mailed on November 2, 2006, *Ferguson Beauregard/Logic Controls, Div. of Dover Resources Inc. v. Mega Systems LLC*, 350 F.3d 1327 (Fed. Cir. 2003), does not hold that "selected to minimize" is analogous to "preselected or predetermined," as is alleged by the Examiner. In that case, the Federal Circuit merely held that "the ordinary meaning of 'predetermine' is 'to determine beforehand.' " *See id.* at 1340. There was no reference whatsoever in *Ferguson Beauregard* to the phrase "selected to minimize." Accordingly, Applicants submit that the Federal Circuit's holding with regard to the term "predetermine" is not germane to the language of the pending claims. Applicants submit, therefore, that the Examiner's characterization of *Ferguson Beauregard* misinterprets the Federal Circuit's actual holding in that case.

Moreover, Applicants respectfully disagree with the Examiner's interpretation of *Whitcher*. In contrast to the presently pending claims, *Whitcher* broadly defines "vapor deposition" as any process of depositing metals and metal compounds by dissipating metal ions from a vaporous medium. Specifically disclosed are physical vapor deposition processes of evaporation and sputtering; additionally, direct and assisted ion beam deposition and chemical vapor deposition are suggested as being useful. *Whitcher*, however, offers no guidance or teaching that any of these processes may be employed to form an as-deposited crystalline film by vacuum deposition while controlling the deposition process to minimize precipitate formation. The reference merely states the specific conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, none of the Examples found in *Whitcher* contain any statement or suggestion either that 1) the vacuum deposited film is crystalline or 2) precipitate formation has, in fact, been controlled.

Relying on *Whitcher*, the Examiner argues in the Final Office Action mailed on November 2, 2006, page 5 that "Whitcher discloses controlling the microcrystal structure" citing Paragraphs 0011, 0028, 0038, 0042 and 0043. The Examiner makes a similar argument in the Advisory Action mailed on February 13, 2007, page 2 citing Paragraphs 0011, 0038, 0040, 0043, 0048, and 0049. Based upon these paragraphs, the Examiner argues that "inherently granular precipitates are controlled, since granular precipitates are an element of a materials [*sic*] microstructure." A careful review of the paragraphs cited by the Examiner fails to corroborate the Examiner's conclusions.

Whitcher Paragraph 0011 states in pertinent part: "[t]he medical devices also have a crystallographic structure that is produced by the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, nanocrystalline and monocrystalline structures." Apart from being internally inconsistent scientifically due to the fact that an amorphous structure is not crystalline[1], this paragraph is merely a recitation that the device may have either a nanocrystalline or monocrystalline structure. The term nanocrystalline is undefined in *Whitcher*. However, it is generally understood to simply be nano-scale polycrystalline structures. *See, e.g.*, online website <http://www.matsceng.ohio-state.edu/~daehn/J_wang/tsld002.htm>, which defines the term "nanocrystalline" as polycrystalline materials with grain sizes of up to about 100nm. The term "monocrystalline" is also undefined in *Whitcher*. However, that term is generally understood to mean "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit." *See, e.g.*, online website <www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm>; *see also* online website <http://www.mancef.org/glossary.htm>, which defines the term "monocrystal" as "Single-crystalline material."

Paragraph 0028 of *Whitcher* states in pertinent part: "[b]y using vapor deposition techniques for the formation of medical devices, the composition, thickness, surface roughness,

[1] Online website <www.dictionary.com> defines the term "amorphous" as "4.Chemistry. not crystalline." Similarly, Online website <http://www.mancef.org/glossary.htm> defines the term "amorphous" as "Material lacking a crystalline orientation and consisting of extremely fine grains, each a few nanometers in size."

and microstructure of devices formed in accordance with the present invention are accurately and precisely controlled." This paragraph is merely a statement of objectives and does not in any manner expressly or implicitly teach what aspects of the microstructure may be controlled, and thus fails to specifically teach that precipitates may be controlled.

Paragraph 0038 of *Whitcher* states in pertinent part: "[t]he removal of impurities and the filtering of particular isotopes are useful in the present invention. The crystalline structure of the metallic medical article may be affected by impurities. Single crystal or monocrystalline materials are more easily formed when levels of impurities are minimized." Again this paragraph is devoid of any teaching that the vacuum deposition process may be controlled in such a manner as to minimize intra- and inter-granular precipitate formation and deposit a crystalline film. Monocrystalline (or single crystal) materials are taught by *Whitcher* as drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure.

Paragraph 0040 of *Whitcher* states in pertinent part: "[i]on beam deposition with mass analysis is a useful vapor deposition process to form monocrystalline medical devices because impurities and mass-species can be controlled. In such a manner a monoisotopic, monocrystalline medical article, such as a stent or a stent wire, may suitably be formed." Again this paragraph is devoid of any teaching that the vacuum deposition process may be controlled in such a manner as to minimize intra- and inter-granular precipitate formation and deposit a crystalline film. The term "impurities," as mentioned in paragraph 0040 of *Whitcher* and described in greater detail in paragraph 0037, actually refers to impurities, such as oxygen, in the "elemental ingot," not to actual precipitates, as has been suggested by the Examiner. In fact, the process disclosed in *Whitcher* exemplifies a conventional nitinol vacuum deposition process as known in the vacuum deposition art. In the conventional prior art nitinol vacuum deposition process, an elemental ingot material, *e.g.*, nitinol, is vacuum deposited as a thin metal film in an amorphous state onto a substrate.[2] Paragraphs 0037 and 0038 and Figure 4B of *Whitcher* teaches

[2] For instance, "Structure and properties of amorphous and nanocrystalline NiTi prepared by severe plastic deformation and annealing," by A. V. Sergueeva, C. Song, R. Z. Valiev, and A. K. Mukherjee, also describes a conventional nitinol vacuum deposition process, wherein there is "formation of homogeneous nanocrystalline

filtering out impurities, such as oxygen, that are contained in elemental ingot, before they are deposited onto a substrate. Because the deposited film is in an amorphous state, *i.e.*, non-crystalline state, an annealing step (synonymous to an aging process) is required to crystallize the thin film. Through an annealing process, precipitates inevitably form and are driven out of the solid solution. Paragraph 0064 of *Whitcher* discloses a method for vacuum depositing a metal film wherein an annealing process is required. Accordingly, *Whitcher's* method of forming a thin metal film through vacuum deposition does not teach, expressly or implicitly, minimizing precipitate formation because *Whitcher's* method requires an annealing step that would inevitably form precipitates.

In contrast to the conventional nitinol vacuum deposition process described in *Whitcher*, the claimed method eliminates the need for an annealing step. The claimed method achieves this by providing means for vacuum depositing a thin film that is in crystalline form as deposited. As a result, an annealing step is not required, and no precipitates are thereby formed. Thus, Applicants teach a method for minimizing precipitate formation that is distinguished from and not taught by *Whitcher*.

Paragraph 0042 of *Whitcher* provides in pertinent part:

> [a] medical device with a nanocrystalline structure is useful because of its enhanced mechanical properties, for instance fatigue resistance and corrosion resistance. A nanocrystalline structure in a biocompatible material with a grain size ranging from about 1 to 500 nanometers is useful as a medical device. Also useful is a biocompatible material with a grain size of about 1 to 100 nanometers. Furthermore, a nanocrystalline structure in a biocompatible material with a grain size of about 1 to 50 nanometers is useful as a medical device. Moreover, a biocompatible material with a grain size of about 1 to 10 nanometers is also useful as a medical.

This teaching merely suggests that nano-scale crystal structures are desirable to enhance mechanical properties of the medical device. No teaching as to how the nanocrystalline structure is formed is found in this paragraph.

---

structure by nanocrystallization of amorphous NiTi." The published article's abstract can be found online at <http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TXD-45FYY9W-6&_user=10&_coverDate=01%2F02%2F2003&_rdoc=1&_fmt=&_orig=search&_sort=d&view=c&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=6ef39f8d3f549e99483cc21dad13467a>.

Paragraph 0043 of *Whitcher*, however, offers the express teaching of how the nanocrystalline structure is formed, wherein it is stated:

> Such nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques can be used to form nanometer sized crystals. [Referring to Paragraph 0041]. Furthermore, the orientation of the nanometer sized grains can be controlled to yield a orderly grain structure with substantially similar crystal orientation. A useful method for forming such structures is through epitaxy where desired material is deposited onto a substrate having a crystalline structure, such as an orientated, nanocrystalline structure, and the deposited material forms a crystalline structure similar to that of the substrate. [Emphasis added].

It is manifestly and unequivocally clear that *Whitcher* teaches depositing a material onto a substrate **in its amorphous state** and after deposition treating or aging the amorphous structure (as expressly taught in Paragraph 0041) to form either a monocrystalline or nanocrystalline structure. This is, without question, different and distinct from the presently claimed invention wherein a film is vacuum deposited as a crystalline layer onto the substrate under conditions which minimize precipitate formation.[3]

Paragraph 0048 of *Whitcher* states in pertinent part: "[a]s described by the aforementioned vapor deposition techniques, metallic layer 115 can be formed to have a range of crystalline morphologies, including a monocrystalline or a nanocrystalline morphology." Again this paragraph is devoid of any teaching that the vacuum deposition process may be controlled in such a manner as to minimize intra- and inter-granular precipitate formation and deposit a crystalline film.

---

[3] *Whitcher* Paragraph 0043 discloses employing epitaxy to form a crystalline structure. However, as widely known to those skilled in the metallurgical arts, epitaxy is a process wholly different from vacuum deposition, which is the process recited in the presently pending claims. Online website <http://en.wikipedia.org/wiki/Epitaxy> discloses that "[e]pitaxial films may be grown from gaseous or liquid precursors. Because the substrate acts as a seed crystal, the deposited film takes on a lattice structure and orientation identical to those of the substrate. This is different from other thin-film deposition methods..." [Emphasis added]. Online website <http://www.answers.com/topic/thin-film-deposition> classifies vacuum deposition and epitaxy as being two wholly distinct thin-film deposition processes.

Paragraph 0049 of *Whitcher* states in pertinent part: "[fi]lter 180 may be used to separate the isotopes of an element or contaminants that may present in source material 120. Desirable filter 180 is a filter containing magnetic and/or electrostatic fields, such as an ExB filter." Again this paragraph is devoid of any teaching that the vacuum deposition process may be controlled in such a manner as to minimize intra- and inter-granular precipitate formation and deposit a crystalline film. As explained above, *Whitcher's* method of forming a thin metal film through vacuum deposition does not teach, expressly or implicitly, minimizing precipitate formation because that method requires an annealing step that would inevitably form precipitates.

The Examiner argues: 1) that "granular precipitates are an element of a materials [*sic*] microstructure;" 2) that "inherently the precipitates are controlled, because Whitcher discloses *selection* of a process *condition;*" 3) that the "amount and size of granular precipitates is dependent upon temp, pressure and rate;" and 4) that "Whitcher also clearly discloses filtering the metal during deposition to control the microstructure, thus inherently granular precipitates would be controlled, minimized, as they are part of the microstructure that would be filtered." The Examiner, however, fails to cite any prior art references that support her arguments. It is well settled that an unsupported assertion or conclusion by the Examiner is insufficient basis for rejecting a claim.

Contrary to the Examiner's assertions, *Whitcher* does not disclose, expressly or implicitly, that vacuum deposition may be controlled to minimize formation of precipitates in the as-deposited crystalline film. In fact, the word "precipitate" does not even appear anywhere in *Whitcher*. Applicants submit that the concept of controlling aspects of the microstructure of a deposited metal is different from the concept of minimizing precipitates in a deposited metal film. As widely known to those skilled in the metallurgical arts, the term "precipitate"[4] is different from the term "microstructure"[5] and different from the term "impurity"[6]. In the

[4] Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

[5] Online website <www.dictionary.com> defines the term microstructure as "the structure of a metal or alloy as observed, after etching and polishing, under a high degree of magnification."

[6] Online website <www.dictionary.com> defines the term impurity as "the quality or state of being impure."

metallurgical arts as they pertain to fabrication of biomaterials, and with particular reference to nickel-titanium shape memory alloys, precipitates are reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from the solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, the metal crystalline structure.

Thus, a "precipitate" is not an "impurity." Rather, it is a reaction product from the solid metal solution. Conversely, an "impurity" is not a "precipitate." Indeed, in paragraph 0037, *Whitcher* clearly notes that "other impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away from the substrate with this method." [Emphasis added]. Based on Applicants' meticulous reading, there is no description whatsoever in *Whitcher* indicating that the "impurities" described in *Whitcher* and referenced by the Examiner, actually refer to precipitates.

In fact, based on *Whitcher's* description, the impurities described in *Whitcher* cannot be precipitates. As previously described, in a conventional prior art nitinol vacuum deposition process, such as *Whitcher's*, an elemental ingot material, *e.g.*, nitinol, is vacuum deposited as a thin metal film in an amorphous state onto a substrate. In such a conventional prior art nitinol vacuum deposition process, an annealing process is necessary to form precipitates and to drive these precipitates out of the solid solution. The precipitates themselves are not formed until commencement of the annealing process, which occurs after the filtering step described in *Whitcher*. Paragraphs 0037 and 0038 and Figure 4B of *Whitcher* teaches filtering out impurities, such as oxygen, that are contained in elemental ingot, before they are deposited onto a substrate. Because *Whitcher's* filtering step occurs before the annealing process, *i.e.*, before actual precipitate formation, the Examiner's interpretation of the passage "impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away..." in Paragraph 0037 of *Whitcher* to encompass a teaching of filtering out precipitates is diametrically opposed to *Whitcher's* actual teachings.

Furthermore, even assuming *arguendo* that *Whitcher's* teaching of controlling microstructure of the deposited metal is in some manner analogous to Applicants' teaching of

minimizing precipitate formation of a deposited metal -- a position that Applicants strongly oppose, the Examiner's anticipation rejection would still be improper because *Whitcher* does not qualify as an enabling prior art reference with regard to Applicants' pending claims. Courts have consistently held that for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel*, Inc. 314 F.3d 1313, 1354 (Fed. Cir. 2003) (stating that "a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled ... a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to 'enable one of skill in the art to reduce the disclosed invention to practice' " and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate." [Emphasis added]. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. And Research*. 345 F.3d 1051, 1054 (Fed. Cir. 2003). In other words, in order "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." [Emphasis added]. *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

In the pending matter, *Whitcher* does not disclose precipitates or precipitate formation, let alone enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize formation of precipitates, as recited in independent claims 39, 47, and 67. Simply put, Applicants submit that *Whitcher's* brief mention of controlling the microstructure of a vacuum deposited metal would not enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize precipitate formation.

For the reasons stated above, Applicants submit that pending claims 39-53 and 67-74 are distinguished from the prior art cited and of record.

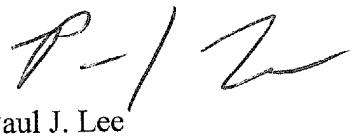
Conclusion

A rejection under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement requires that the Examiner establish by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. The description of the pending application clearly establishes that at the time the original application was filed, Applicants had possession of a method of manufacturing an endoluminal stent comprising, *inter alia*, the step of depositing a crystalline film layer. Thus, the Examiner's rejection based on the written description requirement is improper and should be withdrawn.

An anticipation rejection under 35 U.S.C. § 102(e) requires that the cited prior art reference must disclose each and every claimed element. *Whitcher* does not teach or suggest every limitation recited in the pending claims on appeal. More specifically, *Whitcher* fails to teach a method of manufacturing an endoluminal stent comprising the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film. Furthermore, *Whitcher* does not enable the teachings for which the Examiner relies upon. Thus, *Whitcher* does not anticipate the pending claims, and the Examiner's anticipation rejection is improper and should be withdrawn.

Accordingly, Applicants submit that pending claims 39-53 and 67-74 are patentable over the art cited and of record.

Respectfully submitted,



Paul J. Lee
Reg. No. 52,420

April 30, 2007

ROSENBAUM & ASSOCIATES, P.C.
650 Dundee Road, Suite 380
Northbrook, Illinois 60062
Tel. 847-770-6000
Fax. 847-770-6006
E-Mail: plee@biopatentlaw.com

Claims Appendix

The following is a listing of the claims on appeal.

Claims 1-38. (Cancelled.)

Claim 39. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing a stent-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to minimize formation of chemical and intra- and intergranular precipitates in the bulk material;

b. defining the plurality of first and second structural elements of the endoluminal stent in the unpatterned metal film; and

c. removing the endoluminal stent from the generally cylindrical substrate.

Claim 40. The method according to Claim 39, further comprising a step of depositing a sacrificial material layer onto the substrate prior to step (a) and removing the sacrificial material layer in order to remove the endoluminal stent from the substrate in step (c).

Claim 41. The method according to Claim 39, wherein step (a) is conducted by ion beam-assisted evaporative deposition.

Claim 42. The method according to Claim 39, wherein step (a) is conducted by sputtering.

Claim 43. The method according to Claim 41, wherein the ion beam-assisted evaporative deposition is conducted in the presence of an inert gas.

Claim 44. The method according to Claim 43, wherein the inert gas is selected from the group consisting of argon, xenon, nitrogen and neon.

Claim 45. The method according to Claim 39, wherein the process condition controlled is deposition rate and the deposition rate is no less than about 20 nm/sec.

Claim 46. The method according to Claim 39, wherein during the deposition of the stent-forming metal, the substrate is rotated.

Claim 47. A method of manufacturing an endoluminal stent capable of radially expanding from a first diameter to a second diameter, and having a plurality of first structural elements defining a longitudinal axis of the stent and a plurality of second structural elements interconnecting adjacent pairs of first structural elements and defining a circumferential axis of the stent, comprising the steps of:

a. vacuum depositing nickel and titanium onto an exterior surface of a generally cylindrical substrate to form an as-deposited generally tubular, crystalline nickel-titanium shape memory film having no less than about 51.5 atomic percent nickel, the vacuum deposition occurring under vacuum deposition process conditions selected to minimize formation of inter- and intra-granular precipitates in the bulk material of the nickel-titanium crystalline film; and

b. removing the endoluminal stent from the generally cylindrical substrate.

Claim 48. The method according to Claim 47, wherein the generally tubular film of nickel-titanium has a composition of between about 51.5 and about 55.0 atomic percent nickel.

Claim 49. The method according to Claim 47, wherein during the deposition of the nickel and titanium, the substrate is rotated.

Claim 50. The method according to Claim 47, wherein a source of the nickel and the titanium to be deposited is a nickel-titanium alloy.

Claim 51. The method according to Claim 47, wherein a source of the nickel and the titanium to be deposited is a binary nickel-titanium alloy.

Claim 52. The method according to Claim 47, further comprising, prior to step (a), a step of imparting a pattern defining the first and second structural elements onto the exterior surface of the substrate, and wherein the pattern is transferred to the tubular film of nickel-titanium during step (a).

Claim 53. The method according to Claim 47, further comprising a step of imparting a pattern defining the first and second structural elements onto the tubular film of nickel-titanium after step (a).

Claims 54-66. (Cancelled)

Claim 67. A method of manufacturing a medical device, comprising the steps of:

a. vacuum depositing a device-forming metal onto an unpatterned, exterior surface of a generally cylindrical substrate to form a generally tubular, unpatterned crystalline metal film under vacuum deposition process conditions selected to substantially eliminate formation of chemical and intra- and intergranular precipitates in the bulk material; and

b. removing the deposited generally tubular metal film from the generally cylindrical substrate.

Claim 68. The method according to Claim 67, further comprising a step of depositing a sacrificial material layer onto the substrate prior to step (a) and removing the sacrificial material layer in order to remove the endoluminal stent from the substrate in step (b).

Claim 69. The method according to Claim 67, wherein step (a) is conducted by ion beam-assisted evaporative deposition.

Claim 70. The method according to Claim 67, wherein step (a) is conducted by sputtering.

Claim 71. The method according to Claim 69, wherein the ion beam-assisted evaporative deposition is conducted in the presence of an inert gas.

Claim 72. The method according to Claim 71, wherein the inert gas is selected from the group consisting of argon, xenon, nitrogen and neon.

Claim 73. The method according to Claim 67, wherein the process condition controlled is deposition rate and the deposition rate is no less than about 20 nm/sec.

Claim 74. The method according to Claim 67, wherein during the deposition of the device-forming metal, the substrate is rotated.

8. Evidence Appendix

None.

9. Related Proceedings Appendix

None. No decisions have been rendered by a court or by the Board in any of the pending appeals identified under Related Appeals and Interferences pursuant to 37 C.F.R. § 41.37(c)(ii).